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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,368	11/03/2003	Joseph M. Pastore	279.632US1	5953

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SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
FLORY, CHRISTOPHER A	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
10/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,368	PASTORE ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER A. FLORY	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,8-11,13-16 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,8-11,13-16 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/16/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1, 4-8, 11 and 14-18 as anticipated under §102(e) by Hill'208 have been considered but are moot in view of the new ground(s) of rejection.

Regarding multi-site pacing, Hill'208 discloses pacing the ventricles by those means well known in the art (column 15, lines 48-50). It is considered that multiple-site ventricular pacing is certainly well known in the field as evidenced by the numerous references cited in the instant application both by the Examiner and the Applicant showing pacing leads with more than one electrode positioned in the ventricle or ventricles.

Regarding the limitations of exertion level and cardiac output adequacy, it is noted that the cited portions of Hill'208 disclose heart rate, an indicator of exertion, separately from cardiac output. It is also maintained that setting the pacing parameters to achieve a normal cardiac output reads on an adequacy of the cardiac output, since normal output at a given level of activity is the most adequate CO to achieve through pacing. Furthermore, the measure and analysis of cardiac output inherently requires a cardiac output sensor.

2. Applicant's arguments filed 16 June 2008 have been fully considered but they are not persuasive. Claims 1, 3-6, 8-11, 13-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams'380 in view of Gross'909.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). On page 7 of the response filed 4 February 2008, Applicant only addresses the Adams'380 reference. In the combination of Adams'380 and Gross'909 clearly discloses measurement of cardiac output and patient exertion level and adjusts parasympathetic stimulation based on these computations as explained in the paragraphs below.

Further, Applicant acknowledges that Adams'380 discloses measuring both exertion level and cardiac output, but does not compute a parameter based on both indicative of adequate cardiac output. It is noted that Adams'380 clearly discloses pacing with the intent of achieving a target heart rate, wherein CO = HR x SV, and wherein said target heart rate is set or determined by the activity/exertion level sensed in the patient. Herein, the current heart rate is seen inextricably as a sensing of cardiac output, and the idea of a target rate indicates an optimal achievement as based on the instant heart rate and current activity/exertion level. Applicant is further directed to the following sections of Gross'909: paragraph [9], [63], [193], [215], [218]; and of Adams'380: abstract; paragraphs [5], [15], [64], [72]; figures 13 and 14.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 4-6, 8, 11, 14-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (US 6,718,208, hereinafter Hill'208).

Regarding claims 1, 4, 11 and 14, Hill'208 discloses an implantable device for delivering cardiac function therapy (abstract) comprising a plurality of pacing channels for delivering pacing pulses to multiple ventricular sites (abstract; column 6, lines 26-47; also column 15, lines 48-50); a parasympathetic stimulation channel for stimulating parasympathetic nerves (column 5, line 55 through column 6, line 19; column 7, line 62 through column 8, line 17); a sensor for measuring cardiac output (column 4, lines 35-44); a controller for controlling the delivery of pacing pulses to multiple ventricular sites (Fig. 1, controller 30; abstract; column 6, lines 26-47); wherein the controller delivers the ventricular pacing to prevent the heart rate slowing below a specified minimum value (abstract); wherein it is taken that the controller modulates delivery of parasympathetic stimulation in accordance with the cardiac output measurement (column 6, lines 9-19). It is noted that although Hill'208 does not expressly disclose multiple ventricular pacing cites, it does disclose that the ventricle is paced as is well known in the field, and it is considered that multiple-site ventricular pacing is certainly well known in the field as evidenced by the numerous references cited in the instant application both by the

Examiner and the Applicant showing pacing leads with more than one electrode positioned in the ventricle or ventricles.

Further regarding claims 1 and 11, in the same field of endeavor, Lovett et al. (US 2002/0091415) discloses that ventricular wall stress and heart rate share an inverse relation, in that an increase of heart rate causes a decrease in pulse pressure and concomitantly a decrease in wall stress (paragraph [72]). Therefore, a therapy modality as described in Hill'208 which increases heart rate also inherently decreases wall stress. Alternatively, Hill'208 teaches of a controller for controlling the delivery of pacing pulses to pacing sites in which the controller can deliver pacing therapy in conjunction with parasympathetic stimulation (see above), which Examiner interprets to be capable of reducing ventricular wall stress given that the Hill'208 device meets all the structural limitations set forth in the instant claims.

Regarding claims 5, 8, 15, and 18, and further regarding claims 1 and 11, Hill'208 discloses delivery of parasympathetic stimulation in response to a heart rate condition sensed by electrodes 210 and 220 in Fig. 2, wherein it is contemplated that heart rate is an indicator of a patient's exertion level. Hill'208 discloses delivering nerve and pacing stimulation to return the heart to a normal cardiac output, or maintain a normal cardiac output (column 4, lines 32-44), wherein a normal cardiac output is considered to be indicative of the adequacy of the cardiac output.

Regarding claims 6 and 16, Hill'208 discloses delivering parasympathetic stimulation when the heart is in a slowed or stopped condition (abstract), wherein a

slowed or stopped condition is representative of being below a specified exertion limit value when heart rate is taken to be a sensed indication of exertion.

5. Claims 1, 3-6, 8-11, 13-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (U.S. 2003/0229380, hereinafter Adams'380) in view of Gross et al. (US 2003/0045909, hereinafter Gross'909).

In regards to claims 1 and 11, Adams'380 discloses an implantable device and method for delivering cardiac function therapy to a patient with multiple electrodes (see for example paragraphs 2, 9 and 12), in which includes and an embodiment comprising a biventricular pacing system (see for example paragraph 55), which is interpreted by Examiner to inherently include multiple pacing channels since the system comprises pacing at multiple sites. Adams'380 also discloses that the device comprises a parasympathetic stimulation system (see for example paragraph 11), which Examiner interprets as including a parasympathetic stimulation channel.

Further regarding claims 1 and 11, in the same field of endeavor, Lovett et al. (US 2002/0091415) discloses that ventricular wall stress and heart rate share an inverse relation, in that an increase of heart rate causes a decrease in pulse pressure and concomitantly a decrease in wall stress (paragraph [72]). Therefore, a therapy modality as described in Adams'380 which increases heart rate (ABSTRACT; paragraphs [5], [6]) also inherently decreases wall stress. Alternatively, Adams'380 teaches of a controller for controlling the delivery of pacing pulses to pacing sites (see for example paragraph 10), in which the controller can deliver pacing therapy in conjunction with parasympathetic stimulation (see for example paragraph 11), which Examiner interprets

to be capable of reducing ventricular wall stress given that the Adams'380 device meets all the structural limitations set forth in the instant claims.

Still further regarding claims 1 and 11, Adams'380 is held to disclose a device capable of delivering stimulation simultaneously, as it meets all of the structural limitations set forth in the claims of the instant application. Alternatively, it would have been obvious to one of ordinary skill in the art at the time of the invention to delivery the therapies in a synchronous manner, since synchronous pacing therapy as well as synchronous pacing and nerve stimulating therapies are well known in the implantable stimulator art.

Still further regarding claim 1, Adams'380 discloses the invention substantially as claimed, but does not expressly disclose parasympathetic stimulation in conjunction with the ventricular pacing stimulation. However, in the same field of endeavor, Gross'909 teaches coupling a parasympathetic nerve stimulation device with an implanted deice for monitoring and correcting the heart rate, e.g. a bi-ventricular pacemaker, in order to increase the heart rate when heart rate is too low (paragraphs [9] and [193]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Adams'380 with the combined stimulation as taught by Gross'909 to provide the Adams'380 invention with the same advantage of being able to selectively increase heart rate with an implanted pacemaker to compensate for a drop in heart rate caused by parasympathetic stimulation.

Still further regarding claim 1, Adams'380 discloses a sensor for measuring cardiac output (see for example paragraphs 10 and 92), wherein the controller is

programmed to modulate the delivery of parasympathetic stimulation in accordance with the measured output (see for example paragraphs 11, 42 and 46). Alternatively, Gross'909 teaches a sensor for measuring cardiac output and modulating the delivery of parasympathetic stimulation in accordance with the cardiac output (paragraphs [9], [63], [98], [193], [215]).

In regards to claims 4 and 14, Adams'380 discloses slowing the heart rate of a patient by parasympathetic stimulation (see for example paragraphs 38 and 39).

In regards to claims 5, 8, 15 and 18, and further regarding claims 1 and 11, Adams'380 discloses monitoring a patient's blood pressure, and the use of an activity sensor for monitoring a patient's exertion level (see for example paragraphs 46, 55 and 64). It is taken that the parameter computed form exertion level and cardiac output is indicative of the adequacy of the cardiac output (paragraphs [9], [63], [98], [193], [215]).

In regards to claims 3 and 13, although Adams'380 teaches of the use of a sensor/circuit for measuring impedance to detect cardiac output (see for example paragraph 46), Adams'380 does not specifically teach of the use a trans-thoracic impedance measuring sensor/circuit. Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Adams'380 to include a trans-thoracic impedance to measure cardiac output, since this type of impedance sensor/circuit is well known in the art as a efficient and effective detector of cardiac output. Alternatively, Gross'909 teaches impedance cardiography, which is taken to include trans-thoracic impedance measurement (paragraphs [97], [215]).

In regards to claims 6 and 16, Adams'380 teaches of the system providing parasympathetic stimulation when the activity level is below a particular value (see for example paragraph 46). Although Adams'380 does not specifically state that parasympathetic stimulation only when the measured activity level is below a particular value, Examiner takes the position that such a requirement would have been an obvious modification to one having ordinary skill in the art at the time of the invention since Adams'380 teaches that it is desirable to induce parasympathetic stimulation to reduce a patient's heart rate (see for example paragraph 11) when the activity level is stabilized (see for example paragraph 46), in order to provide effective and efficient parasympathetic stimulation.

In regards to claims 9 and 19, Adams'380 does not specifically state the use of a minute ventilation sensor or an accelerometer, for an exertion level sensor; however, Adams'380 does teach that the activity sensor can be one of a multiple types of exertion/metabolic level sensors (see for example paragraph 64). Thus, Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Adams'380 to include a minute ventilation sensor, since these are commonly known activity/exertion sensors that can be used to efficiently and effectively measure a patient's metabolic demand.

Regarding claims 10 and 20, Gross'909 discloses that the exertion sensor is an accelerometer for measuring the motion of the subject (paragraphs [95], [193]).

6. Claims 3, 9, 10, 13, 19 and 20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hill'208.

In regards to claims 3 and 13, Hill'208 teaches of the use of a sensor/circuit for measuring impedance to detect cardiac output as explained above, Hill'208 does not specifically teach of the use a trans-thoracic impedance measuring sensor/circuit. Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Hill'208 to include a trans-thoracic impedance to measure cardiac output, since this type of impedance sensor/circuit is well known in the art as a efficient and effective detector of cardiac output.

In regards to claims 9, 10, 19 and 20, Hill'208 does not specifically state the use of a minute ventilation sensor or an accelerometer for an exertion level sensor. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught Hill'208 to include a minute ventilation sensor or accelerometer, since these are commonly known activity/exertion sensors that can be used to efficiently and effectively measure a patient's metabolic demand.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christopher A. Flory/

15 October 2008

/George Manuel/
Primary Examiner